

R E M A R K S

Claims 4-14 and 24-25 are currently pending. The pending claims have been rejected under 35 U.S.C. §101 (claims 6-8) and § 112 (claims 6-14). Applicants have canceled claims 1-25 and replaced them with new claims 26-39. Applicants maintain that the new claims more particularly point out and distinctly claim the subject matter which applicants regard as the invention. The subject matter encompassed by the new claims is fully supported by the specification. No new matter is added. For reasons detailed below, applicants believe the rejections should be withdrawn and the claims allowed to issue.

1. The Objection to the Claims

Claim 7 is objected to by the Examiner because the claim recites the phrase “sequences ... which are degenerated ....” The Examiner maintains that it appears that this is a typographical error and applicants meant to recite “degenerate.” Additionally, claims 6-7 and claims 8-14 all of which depend from claims 6 and 7 are objected to because claims 6-7 depend from non-elected claims.

Applicants have canceled claims 6-7 and replaced them with new claims thereby rendering the objections of the Examiner moot.

2. The Claims as Amended are not Directed to Non-Statutory Matter

Claims 6-8 are rejected under U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Claims 6-8 are drawn to “DNA sequence encoding ...” which reads on a product of nature. Amending the claim to recite “An isolated polynucleotide encoding ...” to show the hand of man would overcome the rejection.

Applicants have canceled claims 6-8 and replaced them with new claims which are directed to “An isolated nucleic acid molecule ....” In view of the amended language of the claim, the rejections under 35 U.S.C. §101 should be withdrawn.

3. The Rejections Under U.S.C. §112, Second Paragraph

Claims 7-12 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. According to the Examiner, claims 6-7 and 11 recite the phrase “either of claims 4 and 5” and “either of claims 9 and 10” respectively, however, it is not clear as to whether applicants are claiming the dependency in the alternative or otherwise rendering the claims indefinite. Additionally, the Examiner maintains that claim 7 recites the phrase “which hybridize,” however, the claim does not recite the specific hybridization conditions under which the polynucleotide has to hybridize rendering the claim indefinite. Further, the Examiner alleges that although claim 8 recites the phrase “characterized by the restriction map as shown in Figure 1” it is unclear as to what characteristics applicants are referring to.

Applicants have canceled claims 7-12. The canceled claims have been replaced with new claims that more particularly point out and distinctly claim the subject matter applicants regard as the invention. In particular, new claim 26 is drawn to an isolated nucleic acid molecule comprising a nucleotide sequence which:

- (i) hybridizes under stringent conditions to the nucleotide sequence of SEQ ID No. 2 wherein said stringent hybridization conditions include

hybridization at temperatures of between 60°C and 70°C and a salt content of 0.5 to 1.5 M; and

- (ii) encodes a polypeptide having amidohydrolase activity capable of hydrolysing (R)-3,3,3-trifluoro-2-hydroxy-2-methylpropionamide of the formula:



Support for new claim 26 can be found on page 9, line 15 through page 10, line 6 of the specification.

New claim 31 is directed to a nucleic acid molecule comprising of a Hind III fragment which contains a nucleotide sequence which:

- (i) hybridizes under stringent conditions to the nucleotide sequence of SEQ ID No. 1 wherein said stringent hybridization conditions include hybridization at temperatures of between 60°C and 70°C and a salt content of 0.5 to 1.5 M; and
- (ii) are characterized by the restriction map as shown in Figure 1.

Support for new claim 31 can be found on page 9, lines 15-32, of the specification.

In view of the amendments to the claims, Applicants respectfully request that the rejections under 35 U.S.C. §112, second paragraph be withdrawn.

#### 4. The Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 10-14 are rejected because the invention appears to employ novel vectors/microorganisms. The Examiner alleges that applicants have described only a single

vector, pPRS2a and a microorganism comprising said vector. The Examiner maintains that the specification is silent regarding the vectors pPRS1b, pPRS4 and pPRS7 and the microorganisms comprising said vectors.

The Examiner notes that applicants have deposited only the microorganism comprising the vector pPRS2a under the terms of Budapest Treaty but there is no indication in the specification as to public availability. As that specific vector has been deposited under the terms of the Budapest Treaty, the Examiner has requested an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the microorganism comprising pPRS2a has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

First, Applicants have canceled all claims which refer to the vector pPRS1b. Second, attorney of record herein states that the microorganism *Escherichia coli* XL1-Blue MRF'®/pPRS2a was deposited as DSM 11635 on June 30, 1997 in compliance with the Budapest Treaty. The deposited microorganism will be irrevocably and without restriction or condition released to the public upon issuance of the patent.

Third, with regard to the deposit of vectors pPRS4 and pPRS7 and microorganisms comprising said vectors, Applicants maintain that such deposits are not required because said vectors can be reproduced following the teachings of the specification. Specifically, as stated on page 29, lines 10-20 of the specification, (i) plasmid pPRS7 represents the subcloning of the 1.52 Kb Dra II/BamHI DNA fragment (see Figure 1) derived from the deposited pPRS2a plasmid into the commercially available vector pBLUESCRIPT-KS®; and

(ii) plasmid pPRS4 represents the subcloning of the 1.91 Kb Pst I/BamHI DNA fragment (see Figure 1) derived from the deposited pPRS2a plasmid into the commercially available vector pBLUESCRIPT-KS<sup>⊕</sup>. Applicants assert that based on the teachings of the specification and routine cloning methods known to those of ordinary skill in the art coupled with the deposit of pPRS2a, the claimed vectors are fully enabled.

Claims 6-9, 11-12 are rejected under 35 U.S.C. §112, first paragraph. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The Examiner alleges that claims 6-9, 11-12 are so broad as to encompass any polynucleotide encoding a polypeptide having amidohydrolase activity and capable of hydrolyzing R-3,3,3-trifluoro-2-hydroxy-2-methylpropionamide of Formula VI, from any source including those that are variants, mutants or functional equivalents or fragments of said polynucleotide or encoding a variant, mutant or functional equivalents or fragments (with or without activity) of said polypeptide, or polynucleotides which simply hybridize to either SEQ ID No. 1 of fragments of the same under any hybridizing conditions.

Applicants have amended the claims to encompass an isolated nucleic acid molecule "capable of encoding a functionally equivalent variant of the amino acid sequence of SEQ ID No. 2 wherein said variant retains the ability to hydrolyze (R)-3,3,3-trifluoro-2-hydroxy-2-methylpropionamide of the formula:

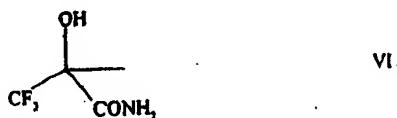


Applicants maintain that based on the disclosures of the amino acid sequence of SEQ ID No. 2 coupled with the disclosure of assays for measuring hydrolysis of (R)-3,3,3-

trifluoro-2-hydroxy-2-methylpropionamide, as set forth in Section 4.2, for example, of the specification one skilled in the art would be capable of identifying those variants encompassed by the claims. All that is required is that any variants of SEQ ID No. 2 be tested for hydrolysis activity as set forth in Section 4.2 of the specification.

Claims 6-9, 11-12 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. According to the Examiner, the claims are directed to a genus of DNA molecules lacking either the structure or the function or both.

As indicated above, Applicants have amended the claims to encompass an isolated nucleic acid molecule “capable of encoding a functionally equivalent variant of the amino acid sequence of SEQ ID No. 2 wherein said variant retains the ability to hydrolyze (R)-3-3,3-trifluoro-2-hydroxy-2-methylpropionamide of the formula:



In this regard, the Examiner's attention is invited to p.9, line 15 through p.5, line 6 of the specification which clearly describes the invention encompassed by the amended claims.

Applicants respectfully request that the rejections under 35 U.S.C. §112, first paragraph be withdrawn.

### CONCLUSION

Entry of the foregoing remarks into the file history of the above identified application is respectfully requested. Applicant believes that the invention described and defined

by the claims is patentable over the rejections of the Examiner. Withdrawal of all rejections and reconsideration of the claims is requested. An early allowance is earnestly sought.

Respectfully submitted,

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